Amendments to the Claim

1. (Previously presented) A process for preparing submicron sized particles comprising:

providing a multiphase emulsion system having an organic phase and an aqueous phase, the organic phase containing a water immiscible organic solvent and a water insoluble or slightly water soluble pharmaceutically effective compound dissolved in the water immiscible organic solvent; and

evaporating essentially all of the water immiscible organic solvent by sonicating the system at a temperature below room temperature, thereby decreasing the solubility of the pharmaceutically effective compound in the system and precipitating particles of the compound from the organic phase into the aqueous phase, the particles having an average effective particle size of less than about 2 μm.

2. (Original) The process of claim 1, wherein the ratio by weights of the organic phase to the aqueous phase is from about 1:99 to about 99:1.

3. (Original) The process of claim 1, wherein the compound is present in an amount by weight of the organic phase from less than about 1% to about 40%.

4. (Previously presented) The process of claim 1, wherein sonicating the system comprises providing a sonication device having a transducer for emitting sonic energy; and exposing the system to said sonic energy sufficient to allow for cavitation to occur.

5. (Previously presented) The process of claim 4, wherein sonicating comprises operating the device at a frequency of from about 1 kHz to about 90 kHz.

6. (Previously presented) The process of claim 1, further comprising adding a surface active compound to either the organic phase, the aqueous phase or to both the organic phase and the aqueous phase.

7. (Original) The process of claim 6, wherein the surface active compound is selected from the group consisting of anionic surfactants, cationic surfactants, nonionic surfactants and biological surface active molecules.

8. (Previously presented) The process of claim 7, wherein the nonionic surfactant is selected from the group consisting of: polyoxyethylene fatty alcohol ethers, polyoxyethylene sorbitan fatty acid esters, polyoxyethylene fatty acid esters, sorbitan esters, glycerol monostearate, polyethylene glycols, polypropylene glycols, cetyl alcohol, cetostearyl alcohol, stearyl alcohol, aryl alkyl polyether alcohols, polyoxyethylene-polyoxypropylene copolymers, polaxamines, methylcellulose, hydroxycellulose, hydroxy propylcellulose, hydroxy propylmethylcellulose, noncrystalline cellulose, polysaccharides, starch, starch derivatives, hydroxyethylstarch, polyvinyl alcohol, and polyvinylpyrrolidone.

9. (Previously presented) The process of claim 8, wherein the anionic surfactant is selected from the group consisting of: anionic surfactant is selected from the group consisting of: potassium laurate, triethanolamine stearate, sodium lauryl sulfate, sodium dodecylsulfate, alkyl polyoxyethylene sulfates, sodium alginate, dioctyl sodium sulfosuccinate, phosphatidyl glycerol, phosphatidyl inositol, phosphatidylserine, phosphatidic acid and their salts, glyceryl esters, sodium carboxymethylcellulose, bile acids and their salts, cholic acid, deoxycholic acid, glycocholic acid, taurocholic acid, glycodeoxycholic acid, and calcium carboxymethylcellulose.

10. (Previously presented) The process of claim 7, wherein the cationic surfactant is selected from the group consisting of quaternary ammonium compounds, benzalkonium chloride, cetyltrimethyl ammonium bromide, chitosans and lauryldimethylbenzylammonium chloride.

11. (Currently amended) The process of claim 7, wherein the surface active biological modifiers are selected from the group consisting of albumin, casein, heparin, and hirudin~~, or other proteins~~.

12. (Previously presented) The process of claim 1, further comprising adding a phospholipid to either the organic phase, the aqueous phase or to both the organic phase and the aqueous phase.

13. (Previously presented) The process of claim 12, wherein the phospholipid is selected from natural phospholipids and/or synthetic phospholipids.

14. (Previously presented) The process of claim 12, wherein the phospholipid is selected from the group consisting of phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, phosphatidylinositol, phosphatidylglycerol, phosphatidic acid, lysophospholipids, egg phospholipid and soybean phospholipid.

15. (Previously presented) The process of claim 12, further comprising adding a surface-active compound to the system.

16. (Previously presented) The process of claim 15, wherein the surfactant is selected from the group consisting of anionic surfactants, cationic surfactants, and biological surface-active molecules.

17. (Previously presented) The process of claim 16, wherein the nonionic surfactant is selected from the group consisting of polyoxyethylene fatty alcohol ethers, sorbitan fatty acid esters, polyoxyethylene fatty acid esters, sorbitan esters, glycerol monostearate, polyethylene glycols, cetyl alcohol, cetostearyl alcohol, stearyl alcohol, poloxamers, polaxamines, methylcellulose, hydroxycellulose, hydroxy propylcellulose, hydroxy propylmethylcellulose, noncrystalline cellulose, polyvinyl alcohol, polyvinylpyrrolidone, albumin, heparin, and hirudin.

18. (Previously presented) The process of claim 16, wherein the anionic surfactant is selected from the group consisting of potassium laurate, triethanolamine stearate, sodium lauryl sulfate, sodium dodecylsulfate, alkyl polyoxyethylene sulfates, sodium alginate, dioctyl sodium sulfosuccinate, phosphatidyl glycerol, phosphatidyl inositol,

phosphatidylserine, phosphatidic acid and their salts, glyceryl esters, sodium carboxymethylcellulose, bile acids and their salts, cholic acid, deoxycholic acid, glycocholic acid, taurocholic acid, glycodeoxycholic acid, and calcium carboxymethylcellulose.

19. (Previously presented) The process of claim 16, wherein the cationic surfactant is selected from the group consisting of quaternary ammonium compounds, benzalkonium chloride, cetyltrimethylammonium bromide, chitosans and lauryldimethylbenzylammonium chloride.

20. (Canceled)

21. (Previously presented) The process of claim 1, wherein the water immiscible solvent is selected from the group consisting of linear, branched or cyclic alkanes with carbon number of 5 or higher, linear, branched or cyclic alkenes with carbon number of 5 or higher, linear, branched or cyclic alkynes with carbon number of 5 or higher; aromatic hydrocarbons completely or partially halogenated hydrocarbons, ethers, esters, ketones, mono-, di- or tri-glycerides, native oils, alcohols, aldehydes, acids, amines, linear or cyclic silicones, hexamethyldisiloxane, or any combination of these solvents

22. (Previously presented) The process of claim 21, wherein the water immiscible solvent has a vapor pressure higher than water at room temperature.

23. (Currently amended) The process of claim 1, wherein generation of the emulsion is accomplished by use of piston gap homogenizers, colloidal mills, high speed stirring, extrusion, manual agitation or shaking, or microfluidization~~, or other high shear conditions~~.

24. (Previously presented) The process of claim 1, wherein the compound is selected from the group consisting of antihyperlipidemics, anesthetics, antiasthamatics, antimicrobials, antifungals, antineoplastics, non-steroidal anti-inflammatory drugs, antihypercholesteremic agents, analgesics, steroidal compounds, antipyretics, antidepressants,

antiarrhtlimics, antianxiety drugs, antimanics, antiarthritics, antihistamines, anti-infectives, water insoluble vitamins, antipsychotics, sedatives, antihypertensive agents, diagnostic agents, anticonvulsants and immunosuppresants.

25. (Previously presented) A process for preparing an aqueous suspension of submicron sized particles comprising the steps of:

providing an organic phase, the organic phase containing a water insoluble or slightly water soluble pharmacologically active compound dissolved in a water immiscible organic solvent;

providing an aqueous phase;

combining the organic phase with the aqueous phase to provide a multiphase emulsion system having said aqueous phase and said organic phase; and

evaporating essentially all of the water immiscible organic solvent by sonicating the emulsion at a temperature below room temperature, thereby decreasing the solubility of the pharmaceutically effective compound in the emulsion and precipitating the compound to form a suspension of submicron sized particles in the aqueous phase, the suspension being essentially free of the water immiscible solvent.

26. (Previously presented) The process of claim 25, wherein the particles are in an amorphous form.

27. (Previously presented) The process of claim 26, wherein the particles have an average effective particle size of less than about 2 μm.

28. (Previously presented) The process of claim 26, wherein the particles have an average effective particle size of less than about 400 nm.

29. (Previously presented) The process of claim 26, wherein the particles have an average effective particle size of less than about 300 nm.

30. (Previously presented) The process of claim 1, wherein the particles have an average effective particle size of less than about 1 μm.

31. (Previously presented) The process of claim 1, wherein the particles have an average effective particle size of less than about 400 nm.

32. (Previously presented) The process of claim 1, wherein the particles have an average effective particle size of less than about 300 nm.

33. (Previously presented) The process of claim 1, wherein the particles have an average effective particle size of less than about 200 nm.

34. (Previously presented) The process of claim 1, wherein the particles have an average effective particle size of less than about 100 nm.

35. (Previously presented) The process of claim 26, wherein the particles have an average effective particle size of less than about 1 μm.

36. (Previously presented) The process of claim 26, wherein the particles have an average effective particle size of less than about 200 nm.

37. (Previously presented) The process of claim 26, wherein the particles have an average effective particle size of less than about 100 nm.

38. (Previously presented) The process of claim 25, further comprising adding a surface-active compound to the system.